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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/783,967

02/16/2001

Daniel E. Alesi

0100/0118

2936

21395

7590

01/21/2004

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,967

Applicant(s)

ALESI, DANIEL E.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-52 is/are pending in the application.
- 4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al (US Pat# 5,746,726) in view of Newby et al (US Pat# 6,436,086) in further view of Burns (US Pat# 5,643,219).

Sweeney discloses a device that includes a body (52) with a needle (14) extending from one end and another end that is attached to a syringe (fig 3). A housing (36) is hingedly (50) attached to the end of the body having the needle and is pivotable to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle (fig 2). Locking means (56) are integrated to the housing for fixedly retaining the needle within the housing once the needle is enveloped by the housing (fig 5). The locking means comprises at least one pair of fingers or hooks (56) that prevent the needle from being removed from the housing once the housing is pivoted to envelope the needle (fig 5). Another locking means (58) is on the body that coacts with the locking means on the housing.

Sweeney meets the claim limitations as described above but fails to include the body being connected to tubing instead of a syringe at the other end from the needle. However, Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a) having a needle (206). Additionally, on the opposite side of the body

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from the needle is connected flexible tubing (208). The other embodiments show the pivotable housing attached to a syringe and a vacutainer port.

At the time of the invention, it would have been obvious to substitute the syringe of Sweeney for flexible tubing as taught by Newby. The devices are analogous in the art and therefore a combination is proper. Additionally, both devices are functional equivalents and utilize a pivotably hinged housing in order to protect a medical technician from being exposed from a needle stick. The motivation for the incorporation would have been in order to provide the device of Sweeney with an alternate means of blood collection thereby enabling more blood to be collected in a container (i.e. a blood bag) at the end of the flexible tubing.

Sweeney in view of Newby meets the claim limitations as described above but fails to include a housing molded to and integrally extending from one of the body or the housing or the housing and body being formed from a mold. However, it is well known in the syringe art to have syringe needle covers that are molded to a base of the needle to be moved into position to cover the needle via a living hinge. Burns, as one of many patents, shows this configuration. Figure 4 clearly shows a one-piece molded unit. A needle housing is connected via a living hinge to a base or body that is fitted to the needle. Burns further shows arms (58) that connect to the base once positioned around the needle to prevent the needle from being re-exposed.

At the time of the invention, it would have been obvious to incorporate the molded construction of Burns into the invention of Sweeney in view of Newby. All three inventions are analogous in the art and with the instant application; therefore, a combination is proper. Additionally, molding a one-piece syringe needle cover to a base for connection with a needle is

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well known in the art. The motivation for making the combination would have been to enhance the manufacturing of the device since the advantages of molding are very well known in the art.

Claims 39-41, 44-46 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby et al in view of Burns.

Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a-204) having a needle (206). It is considered inherent that the body includes a through passage connecting its one end to its other end in light of the fluid delivery function of the device. The proximal portion of the body (204) has wings (see figure 17). Additionally, on the opposite side of the body from the needle is connected flexible tubing (208). A locking mechanism, analogous to applicant's locking means, is best seen in figure 16. Hooks or fingers (194) hold the housing in the retaining needle position by their connection with element 118. Furthermore, figure 17 best shows the intravenous device body construction where the body is integrally (meaning used: "formed as a unit with another part") attached to the tubing, needle and housing. The definition of the term integral appears below in the Response to Arguments. Finally, the device is considered one-piece once assembled and during use.

Newby meets the claim limitations as described above but fails to include a housing molded to and integrally extending from one of the body or the housing or the housing and body being formed from a mold. However, it is well known in the syringe art to have syringe needle covers that are molded to a base of the needle to be moved into position to cover the needle via a living hinge. Burns, as one of many patents, shows this configuration. Figure 4 clearly shows a one-piece molded unit. A needle housing is connected via a living hinge to a base or body that is

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fitted to the needle. Burns further shows arms (58) that connect to the base once positioned around the needle to prevent the needle from being re-exposed.

At the time of the invention, it would have been obvious to incorporate the molded construction of Burns into the invention of Newby. Both inventions are analogous in the art and with the instant application; therefore, a combination is proper. Also, Newby discloses that "it is within the purview of the present invention to include any structure for connecting the shield to the collar so that the shield may be pivoted...including living hinges". See Newby 2:15-20. Additionally, molding a one-piece syringe needle cover to a base for connection with a needle is well known in the art. The motivation for making the combination would have been to enhance the manufacturing of the device since the advantages of molding are very well known in the art and Newby provides motivation in asserting that a living hinge (i.e. molding the two pieces together) is an acceptable connection.

Response to Arguments

Applicant's arguments with respect to claims 39-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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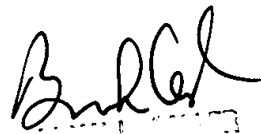
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams *CSW*
January 9, 2004


Brian Casler